

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL No. 1456

Civil Action No. 01-12257-PBS

Hon. Patti B. Saris

THIS DOCUMENT RELATES TO:

*United States ex rel. Edward West, et al., v.
Ortho-McNeil Pharmaceutical, Inc. and
Johnson & Johnson.*

CIVIL ACTION NO. 06-12299-PBS

**REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS
PLAINTIFF'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION**

Plaintiff Edward West makes several significant concessions in his response to defendants' motion to dismiss the First Amended Complaint for lack of subject matter jurisdiction. Specifically:

- The allegations and transactions underlying West’s False Claims Act (“FCA”) claims were “publicly disclosed” before West filed his lawsuit;
- West’s claims are “based on” the public disclosures;
- West is not the original source of the public disclosures, which bars his claims under the False Claims Acts of California, Hawaii, Nevada, and D.C.;
- West is not an “original source” of information that would substantiate an FCA cause of action premised on the alleged inflation or misrepresentation of AWP; and
- West’s claims on behalf of the states of Nevada and Hawaii are barred because those states are pursuing identical claims against these same defendants in separate lawsuits.

Notwithstanding these concessions, West argues that his case should not be dismissed for three reasons. First, West argues that even though his allegations that the

defendants inflated AWP's were publicly disclosed before he filed his Complaint, the Complaint supports another theory of liability, that was not publicly disclosed, premised on alleged violations of the Anti-Kickback Statute. Second, West argues that the interpretation of "based upon" adopted by a majority of courts, including this one, is wrong and should be reconsidered. Third, West argues that even if his claims are based upon publicly disclosed allegations, he is an "original source." As we explain below, none of West's arguments have merit.

I. THE COURT LACKS SUBJECT MATTER JURISDICTION OVER WEST'S CLAIMS BECAUSE THEY ARE BASED ON PUBLICLY DISCLOSED ALLEGATIONS.

A. The Allegations On Which West's Claims Are Based Were "Publicly Disclosed" Before West Filed His Lawsuit.

West does not dispute that his claim that the defendants "manipulat[ed] of the average wholesale price ("AWP") of their pharmaceuticals was publicly disclosed before West commenced this action." West's Brief in Opposition ("Response") at 3. However, West argues that certain allegations in the Complaint also support a separate theory of False Claims Act liability premised on the payment of "bribes" (West's characterization of discounts and rebates for drug purchases), in violation of the Anti-Kickback Statute. *Id.*

West's argument rests on a fundamental misunderstanding of the False Claims Act. The public disclosure bar focuses on the "allegations or transactions" underlying the plaintiff's claims – not on how many legal theories premised on those same facts the plaintiff can conjure up. *See* 31 U.S.C. § 3730(e)(4)(A)). The same allegations that West concedes "publicly disclosed" West's claims that the defendants "manipulat[ed] the average wholesale price ('AWP') also publicly disclosed West's recharacterized "kickback"-based claims. For example, the Master Amended Class Action Complaint (MACC) filed on September 6, 2002 – over a year before West filed his Complaint – alleged that these defendants provided illegal "rebates, hidden

price discounts and/or other unlawful financial inducements” to purchasers to induce the purchase of drugs. MACC ¶ 4. *See also id.* ¶¶ 160, 165, 340(g), 361. Likewise, the State of Nevada alleged that the defendants have “utilized other improper inducements to stimulate sales of its drugs,” such as “off-invoice inducements” and “substantial discounts” to purchasers. *See* State of Nevada’s Amended Complaint ¶ 12 (MDL 1456 Docket No. 922). Thus, the “allegations or transactions” on which West’s False Claims Act counts are based were “publicly disclosed” before West filed his Complaint, regardless of whether West characterizes his claims as premised on “AWP inflation” or a violation of the Anti-Kickback Statute.

B. West’s Allegations Were “Based Upon” The Public Disclosures

West concedes that his claims are “based upon” the public disclosures, as that phrase has been interpreted by the majority of courts – including this one. *See United States ex rel. O’Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 92 (D. Mass. 2001); Response at 5. Under the majority interpretation, West’s claims are barred because they are “similar to or the same as those that have been publicly disclosed,” regardless of whether West subjectively based his allegations on the publicly disclosed information. *O’Keeffe*, 131 F. Supp. 2d at 92.

Recognizing that he has no argument to make under the existing legal standard, West asks the Court to change it. Specifically, West contends that the Court should reject the “majority view” interpretation of “based upon” based on the Supreme Court’s recent opinion in *Rockwell International Corp. v. United States*, 127 S. Ct. 1397 (2007), which, West contends, “has undermined this Court’s reading of the term ‘based upon.’” Response at 5. West also argues that other cases decided since this Court’s ruling in *O’Keefe* cast doubt on the wisdom of the majority view adopted by this court.

1. Rockwell Is Irrelevant To This Motion.

The sole issue addressed by the Supreme Court in *Rockwell* was the interpretation of the “original source” provision of the False Claims Act, located at 31 U.S.C. § 3730(e)(4)(B). The Supreme Court did not address the interpretation of the “based upon” language in 31 U.S.C. § 3730(e)(4)(A) – a point expressly stated in the majority opinion. 127 S. Ct. at 1405 (“As this case comes to the Court, it is conceded that the claims on which [the relator] prevailed were based upon publicly disclosed allegations within the meaning of § 3730(e)(4)(A)”) (emphasis added). *Cf. U.S. ex rel. Maxwell v. Kerr-McGee Oil & Gas Corp.*, No. 04- 01224, 2007 WL 1686734, at *2 (D. Colo. June 8, 2007) (“*Rockwell* does not purport, either expressly or by implication, to alter the Tenth Circuit's standard applied by this Court with respect to when a claim is ‘based upon’ a public disclosure.”) (attached as Exhibit A).

Nevertheless, West reads into the *Rockwell* decision a general command to federal courts “in favor of finding federal subject matter jurisdiction.” Response at 10. West does not provide much explanation for this interpretation of the Court’s holding, which would seem at odds with the fact that, in *Rockwell*, the Court interpreted the False Claims Act to *deprive* federal courts of subject matter jurisdiction over the relator’s claims. *See Rockwell*, 127 S. Ct. at 1412. Nor have other federal courts interpreted *Rockwell* as loosening the reins on federal subject matter jurisdiction. *See, e.g., Choice Hotels Intern., Inc. v. Shiv Hospitality, L.L.C.* --- F.3d ---, 2007 WL 1763536, at *2 (4th Cir. June 20, 2007) (“As a court of limited jurisdiction, we are obligated to satisfy ourself of our jurisdiction as well as that of the district court”); *Oglala Sioux Tribe v. C & W Enterprises, Inc.*, 487 F.3d 1129, 1130 (8th Cir. 2007) (“Federal courts are courts of limited jurisdiction.”)

2. The Majority View Interpretation of “Based Upon” Is Still The Correct One.

The First Circuit still has not ruled on the proper interpretation of “based upon” under the False Claims Act. Nevertheless, West argues that the majority view interpretation (this Court’s interpretation) is inconsistent with First Circuit precedent “to construe the public disclosure bar in favor of federal subject matter jurisdiction.” Response at 7. In support of this argument, West cites a single case, *United States ex rel. Prawer v. Fleet Bank of Maine*, 24 F.3d 320 (1st Cir. 1994), which was decided seven years before this Court’s decision in *O’Keefe*, and which addressed an entirely separate provision of the False Claims Act (31 U.S.C. § 3730(e)(3)) that is not at issue here. Nothing in *Prawer* provides any basis for concluding that this Court got it wrong when it adopted the majority view in *O’Keefe*.

Nor have there been any other developments that warrant revising the conclusion that the majority view of “based upon” is the correct one. While West asserts that *O’Keefe* is at odds with “a majority [of courts] in this District who have addressed the issue” (Response at 5) – he cites only a single case, *United States ex rel. Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6 (D. Mass. 2006) (Tauro, J.). Not only is that case not binding on this Court, it is inconsistent with the growing chorus of courts adopting the majority view since *O’Keefe* was decided. *See, e.g., United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 334 (3d Cir. 2005); *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 975 (6th Cir. 2005); *Minnesota Ass’n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1047 (8th Cir. 2002); *Maxwell*, 2007 WL 1686734 at *2; *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 70-71 (D. Conn. 2006); *United States ex rel. Kinney v. Stoltz*, No. 01-1287 2002, WL 523869, at *6 (D.

Minn. Apr. 5, 2002). These courts join the numerous others that had already adopted the majority view when *O’Keefe* was decided.¹

In sum, if the legal landscape since *O’Keefe* has changed at all, it reflects an even stronger affirmation of the correctness of the majority view interpretation of “based upon.” This Court’s justifications for adopting the majority view remain just as sound today as they were six years ago:

[The majority’s] reading of “based upon” is consonant with the structure and policies of the FCA. The minority’s interpretation of the words “based upon” would contravene the congressional policy of prohibiting *qui tam* actions where the government has sufficient information to pursue the false claim itself. Indeed, allowing a relator suit after the same allegations or transactions have entered the public domain may have the perverse effect of “either pressur[ing] the government to prosecute cases when it has good reasons not to or reduc[ing] the government’s ultimate recovery.” Moreover, as several courts have pointed out, a literal reading of the statute that places separate emphasis on the words “based upon” would essentially render the public disclosure bar’s “original source” exception superfluous.

131 F. Supp. 2d at 93 (internal citations omitted).

C. West Is Not An “Original Source”

Because West’s FCA claims premised on AWP inflation are “based on publicly disclosed information,” West must establish that he is an “original source” of the information underlying his claims alleging AWP inflation. Opening Mem. at 10-12.

¹ See *United States ex rel. Biddle v. Bd. of Trs. of the Leland Stanford, Jr. Univ.*, 161 F.3d 533, 537-40 (9th Cir. 1998); *United States ex rel. McKenzie v. BellSouth Telecom., Inc.*, 123 F.3d 935, 940 (6th Cir. 1997); *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 652-655 (D.C.Cir. 1994); *Cooper v. Blue Cross and Blue Shield of Florida, Inc.*, 19 F.3d 562, (11th Cir. 1994); *United States ex rel. John Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2nd Cir. 1992); *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 552 (10th Cir. 1992).

1. West Was Not The Source Of The Public Disclosures.

The False Claims Acts of California, Hawaii, Nevada, and D.C. require West to prove that he is the person “whose information provided the basis or caused the making of the investigation, hearing, audit or report that led to the public disclosure” in order to qualify as an original source. *See* West's Ann.Cal.Gov.Code § 12652(d)(3)(B) (California); H.R.S. § 661-28 (Hawaii); N.R.S. § 357.100(2) (Nevada); DC St. § 2-308.15(b)(2)(B) (D.C.). West does not contend that he is the source of the public disclosures contained in the numerous government reports, the MACC, or the lawsuit filed by the State of Nevada that contain the publicly-disclosed allegations or transactions on which West's claims are based. Because West is clearly not an original source under the False Claims Acts of California (Count III), Hawaii (Count VI), Nevada (Count IX) and the District of Columbia (Count XIII), those claims must be dismissed.

2. West Lacks Direct and Independent Knowledge of Key Facts.

To prove that he is an “original source” under the federal False Claims Act and the remaining State statutes, West must demonstrate that he has direct and independent knowledge of facts substantiating his claims that the defendants reported false or inflated AWP. West has not made that showing. West concedes in the Complaint that he lacks either direct or independent knowledge of the core factual allegation underlying his claims premised on AWP inflation. Specifically, West concedes that he lacks direct and independent knowledge of AWP allegedly inflated by the defendants, or the “true” costs of the drugs – *i.e.*, West lacks knowledge of even a single “spread” demonstrating that AWP were inflated. Complaint ¶ 77. West cannot have “direct and independent” knowledge that defendants inflated AWP when he concedes he has no knowledge of pricing information at all.

West argues that even if he doesn't have "direct and independent knowledge" of any pricing information, he has direct and independent knowledge of alleged "kickbacks," which (he contends), are sufficient to support his claims of AWP inflation. Response at 10-11. This argument should be rejected for two reasons. First, this attempted bootstrapping is inconsistent with West's earlier argument that his claims premised on the basis of kickbacks are entirely distinct from claims premised on "AWP inflation." *See, e.g.*, Response at 4 ([T]he bribes were part of two separate schemes"); *see also id.* (referring to West's allegation of AWP manipulation as "a different transaction entirely"). If, as West contends, he has pled kickback-based claims that are distinct from "AWP inflation" claims, it follows that the two types of claims must have distinct elements. Indeed, this Court has held that knowledge (or some other reasonably specific indication) of an actual "inflated" AWP is a threshold requirement for pursuing claims alleging inflation of AWP. *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at *59-60, 66.²

Second, West's allegations concerning alleged kickbacks are largely second-hand or speculative, rather than based on "direct and independent knowledge." For example, while West alleges that sales representatives "were instructed" to encourage hospitals not to report rebates from OMP (Complaint ¶ 75), he does not allege that he (or anyone else) actually did so. *See also id.* ¶ 84 ("sales representatives were instructed . . ."). Moreover, given that many of West's allegations concerning kickbacks involve remuneration to hospitals, which are not reimbursed on the basis of AWP, West fails to explain how his allegations concerning kickbacks support claims premised on alleged misrepresentation of AWP.

² While the Court has imposed this requirement in the context of requiring claims to be pled with specificity under Rule 9(b), it is equally, if not more important, that the plaintiff be able to make such a showing where the Court's subject matter jurisdiction hinges on it.

West also asks the Court to infer that he has “direct and independent knowledge” of the information on which his claims are based because he was fired by OMP in 1999, before the public disclosure of the allegations and transactions on which his claims are based. Response at 10. This argument is a *non sequitur*. The relevant inquiry under the False Claims Act is not when, in relation to the public disclosures, West was employed by the defendants, but rather when, in relation to the public disclosures, West filed his Complaint.

West did not file his complaint until November 2003, meaning that the information contained in the numerous public disclosures dating back to the 1980s are an equally likely source of West’s purported “knowledge” of AWP inflation. As noted previously, the relevant public disclosures date back years before West first began working for defendant OMP. *See* Opening Mem. at 7-8. Indeed, as the Court recently noted, since at least 1997, “most knowledgeable insiders understood that AWP did not reflect the average sales price to providers.” *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257-PBS, 2007 WL 1774644, at *11 (D. Mass. June 21, 2007); *see also id.* at *12 (“A 1984 OIG report involving self-administered drugs stated [that] AWP cannot be the best-or even an adequate-estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists’ invoices.”); *id.* (“In 1992, the OIG began to focus on the shortcomings of AWP as a reimbursement benchmark for Medicare physician-administered drugs.”) West’s complaint indisputably was filed years after the relevant public disclosures.

II. WEST’S CLAIMS ON BEHALF OF THE STATES OF NEVADA AND HAWAII ARE BARRED BECAUSE THEY ARE PURSUING THEIR OWN LAWSUITS.

West does not dispute that his causes of action under the False Claims Act of Hawaii (Count VI) and Nevada (Count IX) are barred because each state is pursuing its own False Claims Act claims against the defendants. *See* Opening Mem. at 13-14. Thus, even if the court concludes that it has subject matter jurisdiction over West's claims, these statutory provisions provide an independent – and undisputed – based for dismissal of West's claims on behalf of Nevada and Hawaii.

III. IF THE COURT CONCLUDES THAT WEST MAY SEPARATELY PURSUE NON-AWP-RELATED CLAIMS PREMISED ON THE PAYMENT OF KICKBACKS, IT SHOULD REMAND THE CASE.

If the Court concludes (as it should) that it lacks subject matter jurisdiction over any FCA claim by West premised on the alleged inflation or misrepresentation of AWP, but that West has asserted a distinct FCA claim premised on the payment of kickbacks over which the Court does have jurisdiction, then the Court should remand this case back to the Northern District of Illinois, where it was originally filed, pursuant to JPML Rule 7.6 (f)(i) (“When the Panel has been advised by the transferee district judge, or otherwise has reason to believe, that pretrial proceedings in the litigation assigned to the transferee district judge are concluded or that remand of an action or actions is otherwise appropriate, an order may be entered by the Clerk of the Panel remanding the action or actions to the transferor district court.”)

The sole basis for West's request for transfer of this case to this MDL – and the sole basis on which that request was granted – was West's contention that his claims were based on AWP inflation, and therefore shared common issues of fact with the other cases pending in this MDL. *See* JPML December 20, 2006 Transfer Order at 1. If the Court lacks jurisdiction to address any claims asserted by West arising out of allegations of alleged AWP inflation, then the original justification for transfer disappears. There is nothing to be gained by coordinating discovery in the other cases pending in the MDL (discovery that is largely complete) with

discovery in West's case, which would focus solely on claims concerning alleged kickbacks – claims that, according to West, “support a completely different fraudulent scheme” than the one on which transfer was based. Response at 4.

Judge Kendall in the Northern District of Illinois is eminently capable of handling any remaining non-AWP-related claims in this case, including deciding the remaining motion to dismiss those of West's claims currently pending before this Court for failure to state a claim or plead with particularity. Indeed, since defendants filed this motion, Judge Kendall issued a written opinion granting defendants' motion to dismiss West's off-label marketing claims, which the JPML severed from the claims transferred to this Court. *See United States ex rel. West v. Ortho-McNeil Pharm., Inc.*, No. 03 C 8239 (N.D. Ill. Jul. 20, 2007) (attached as Exhibit B).

CONCLUSION

WHEREFORE, defendants Johnson & Johnson, Inc. and Ortho-McNeil Pharmaceutical, Inc. respectfully request that the Court dismiss West's claims with prejudice for lack of subject matter jurisdiction.

Date: July 23, 2007

Respectfully submitted,

ORTHO-MCNEIL PHARMACEUTICAL,
INC. and JOHNSON AND JOHNSON, INC.

By: /s/ Scott D. Stein
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CERTIFICATE OF SERVICE

I, Jordan S. Ginsberg, certify that on July 23, 2007, I electronically filed the foregoing document with the Clerk of the Court for the District of Massachusetts using the court's CM/ECF system.

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